

## REMARKS

Claims 1-22 are pending in the subject application. Claims 1, 6, 14-16, 18, and 19 have been amended, claim 7 has been canceled, and claim 23 is added. Applicants submit that the amendments herein introduce no new matter, support therefore being found throughout the application and drawings as originally filed.

The Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration based on the amendments and the following remarks.

### 1. 35 U.S.C. §102 Rejections

Claims 1 and 19 are rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,725,493 to Avery et al. (hereinafter "Avery"). Applicants respectfully traverse.

Applicants recite, in amended claim 1, a subretinal delivery device comprising a reservoir and a cannula extending from the reservoir. As set out, the cannula configured to extend from the reservoir through the retina into a subretinal space when the reservoir is disposed exterior the eye on the sclera or when the reservoir is disposed within the eye. As further set out, an agent in the reservoir is released through the cannula to the eye subretinally.

Claim 19, as amended, recites a method for the treatment of ocular conditions comprising the steps of implanting the agent delivery device of claim 1 into the eye such that the reservoir is disposed exterior the eye on the sclera or such that the reservoir is disposed within the eye, with the cannula extending from the reservoir through the retina into a subretinal space; and allowing the agent in the reservoir to be delivered to the eye via the cannula subretinally.

Avery, on the other hand, describes a device and method for intravitreal medicine delivery. In particular, Avery provides a housing 80 that is positioned on the outer surface of an eyeball and, as such, is configured to conform to the outer curvature of the eyeball (e.g. by having a concavo-convex shape and a low profile)(see col. 4, lines 38-57). A tube 140 extends from the housing 80 along the outer surface of the eyeball. A tubular elbow 160 is attached to the distal end of the tube 140 and includes an intravitreal extension 164 that projects at an angle so as to be insertable within the eye (see col. 6, line 34-46; col. 6, line 58 – col. 7, line 22). Medicine in the reservoir is thereby released through the intravitreal extension into the vitreous cavity.

Clearly, Avery does not teach or suggest a subretinal delivery device having a cannula configured to extend from a reservoir through the retina into a subretinal space when the reservoir is disposed exterior the eye on the sclera or when the reservoir is disposed within the eye, such that an agent in the reservoir is released through the cannula to the eye subretinally. Avery also does not teach or suggest a method for the treatment of ocular conditions by implanting a delivery device into the eye such that a reservoir is disposed exterior the eye on the sclera or such that the reservoir is disposed within the eye, with a cannula extending from the reservoir through the retina into a subretinal space; and allowing the agent in the reservoir to be delivered to the eye via the cannula subretinally.

Accordingly, it is respectfully submitted that claims 1 and 19 are patentable over Avery. Reconsideration and withdrawal of the rejection is respectfully requested.

Further, Applicants note that Avery at least does not teach or suggest an intraocular delivery device comprising a reservoir and a cannula extending from the reservoir, wherein the cannula is configured to extend from the reservoir into a treatment site when the reservoir is disposed within the eye, and wherein an agent in the reservoir is released through the cannula directly to the treatment site, as recited in new claim 23.

Rather, Avery describes a device wherein the reservoir is configured so as to be positioned on the outer surface of an eyeball and so as to conform to the outer curvature of the eyeball. Thus, claim 23 is also patentable over Avery.

## 2. 35 U.S.C. §103 Rejections

Claims 2-18 and 20-21 are rejected under 35 U.S.C. §103(a) over Avery and U.S. Patent No. 5,454,796 to Krupin (hereinafter “Krupin”) or U.S. Patent No. 5,370,607 to Memmen (hereinafter “Mennen”). Applicants respectfully traverse.

As set forth above, claims 1 and 12 are not taught or suggested by Avery. Further, neither Krupin nor Memmen remedy the above-noted deficiencies in Avery.

Krupin describes a drainage device and method for lowering intraocular pressure in the eye by draining fluid from the anterior chamber of the eye. Krupin’s device includes an oval shaped plate 12 with an attached elongate tube 14. According to Krupin, the plate 12 is configured so as to nest on the outer surface of the eye between adjacent rectus muscles of the eye, and the tube 14 is configured so as to extend from the plate 12 into the anterior chamber of the eye such that fluid can be withdrawn from the anterior chamber of the eye through the tube 14, and out of the eye into the plate 12.

Similarly, Memmen describes a device and method for treating glaucoma by draining fluid out of the anterior chamber of the eye. Memmen’s device includes a reservoir 20 configured so as to be positionable along the outer surface of an eyeball, and a drainage tube 60 configured so as to extend from the reservoir 20 into the anterior chamber of the eye such that fluid can be withdrawn from the anterior chamber of the eye through the tube drainage tube 60, and out of the eye into the reservoir 20.

Thus, clearly no combination of Avery, Krupin, and Memmen would provide Applicants' subretinal delivery device and methods of treatment.

Accordingly, it is respectfully submitted that claims 1 and 19 are patentable over Avery, Krupin, and Memmen. Claims 2-6, 8-18 and 20-22 depend from claims 1 and 19 and, thus, also are patentable over Avery, Krupin, and Memmen. Reconsideration and withdrawal of the rejection is respectfully requested.

Further, like Avery, Krupin, and Memmen at least do not teach or suggest an intraocular delivery device comprising a reservoir and a cannula extending from the reservoir, wherein the cannula is configured to extend from the reservoir into a treatment site when the reservoir is disposed within the eye, and wherein an agent in the reservoir is released through the cannula directly to the treatment site, as recited in new claim 23. Thus, claim 23 is also patentable over Avery, Krupin, and Memmen .

### **CONCLUSION**

In view of the forgoing, Applicants believe the pending application is in condition for allowance. Early and favorable action is requested.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**.

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Respectfully submitted,

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